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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,028	10/25/2000	Vincent P. Stanton JR.	11926-112001	3430

7590 08/21/2002

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

13

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,028

Applicant(s)

STANTON, VINCENT P.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (CPA) (Paper NO. 11) filed on June 17, 2002. The request for CPA is accepted and is established with the status of the application as follows:

- a. the filling date of this CPA is established as 10/25/2000;
- b. Claims 10-16 are pending.

2. Applicants' response to the earlier office action (Paper No. 12) filed on June 17, 2002 has been entered.

3. Applicants' petition to correct inventorship and declaration from the inventors (Paper No. 12) has been entered.

4. Applicant's response to the office action (Paper No.6) is fully considered and deemed not persuasive.

5. The following is the rejection made in the previous office action under 35 U.S.C. 102(b):

Claims 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Tyagi et.al. (USPN. 6,277,607).

Tyagi et al. teach a method for amplification of a DNA molecule wherein a first nucleic acid molecule having a mutated nucleotide at the polymorphic site is amplified to a greater extent than a second nucleic acid having a different nucleotide at the said polymorphic site (see column 3, lines 51-62, column 12, lines 47-67 and column 13, lines 1-26). Tyagi et al. also disclose that the method comprises (i) contacting a sample of DNA with a pair of primers, one of which is complementary to a nucleic acid strand and the other of which is complementary to the other strand, and amplifying the nucleic acid, thereby the polymorphic site with mutated

Art Unit: 1637

nucleotide is amplified to a greater extent than the second or other nucleic acid molecule with a different nucleotide at the said site (see column 3, lines 51-62, column 8, lines 8-20, column 12, lines 47-67 and column 13, lines 1-26); Upon amplification the said primers form a stem-loop structure (hairpin stem) (see column 8, lines 39-66); DNA could be single-stranded or double-stranded derived from human (see column 11, lines 5-67, column 12, lines 1-44); a series of polymerase chain reactions could be carried out to perform amplification of plurality of polymorphic sites (see column 12, lines 46-67, column 13, lines 1-25); determination of relative proportion of mutant and wild-type sequences in the amplified products (see column 8, lines 8-20). Thus the disclosure of Tyagi et al. meets the limitations in the instant claims.

Response to Arguments:

Applicant's arguments with respect to the rejection made under 35 U.S.C. 102(b) claims 10-16 have been considered and are found not persuasive. Applicants argue that the method claimed is distinct from the method in the prior art. This argument is unavailing for two reasons. First, the prior art references teach each of the limitations found in the claims. Second, the claim is of the open "comprising" format, which permits the inclusion of additional elements, so that any additional steps are permitted in the claim.

Applicants' particular argument that the prior art of the record, Tyagi et al. method of differential amplification or biasing a DNA amplification utilizes primers hybridize differentially to the two different nucleic acid molecules whereas the primers of the instant invention are designed to flank the polymorphic site, and do not hybridize. Applicants correctly argues that the primers of the instant invention flank the polymorphic site, the primers of Tyagi et al. encompass overlapping regions and do permit the primers to hybridize differentially to the

Art Unit: 1637

different nucleic acid molecules depending on the presence or absence of polymorphic site. Thus the limitation 'flank' is broad and does not exclude the possibility of overlapping regions specifically the "flank" permits the inclusion of primer binding or hybridizing regions to the polymorphic site. Further, Applicants argue that the method of Tyagi et al. reduces differential amplification and teaches far away from the instant invention enhancing the differential amplification. This argument is found not persuasive because Tyagi et al. does teach enhancing differential amplification. Tyagi states that the difference in threshold cycles decreases as the proportion of one type of template is raised and the proportion of the other type of template is decreased (see column 13, lines 1-25). Thus the method of Tyagi et al. does enhance biasing or differential amplification. Therefore the rejection is maintained herein.

No claims are allowable.

Conclusion

This is a RCE of applicant's earlier Application No. 09/720,206. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1637

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{SPC}
Suryaprabha Chunduru

August 14, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER